

## **ATTACHMENT A**

### **REMARKS**

Claims 16-23 stand pending in the present application. By this Amendment, Applicant has canceled claims 1-15 and added new claims 16-23 where claims 16-22 correspond to now canceled claims 7, 8, 9, 10, 12, 7 and 14, respectively. Applicant respectfully submits that the present application is in condition for allowance based on the discussion which follows.

In the Office Action, the Examiner indicated that the references cited in the International Search Report were considered but would not be listed on any patent resulting from this application because they were not provided on a separate listing in compliance with 37 C.F.R. § 1.98. Contemporaneously filed with this Amendment, Applicant has submitted a separate listing of the reference cited in the International Search Report on a PTO-1449 form so that the reference will be printed on the patent resulting from this application.

Further, in the Office Action it was noted that the specification should include reference to the International patent application of which this is a 371 (national stage) patent application. By this Amendment, Applicant has amended the specification to include such a reference. In addition, the specification was objected to for failing to include a section heading entitled "Brief Description of the Drawings". By this Amendment, Applicant has amended the specification on page 9 to include the section heading for the Brief Description of the Drawings thereby obviating the objection to the specification.

Finally, the specification was objected to for allegedly not including an abstract of the disclosure as required by 37 C.F.R. § 1.72(b) for failing to have an abstract on a separate sheet as required (see Section 4 of the June 20, 2003 Office Action). However, this requirement in a national stage (371) application is "improper" (see MPEP § 1893.03(e)) since the PCT published application contains an abstract on a separate page. Therefore, Applicant respectfully requests that the Examiner withdraw the objection to the specification for failure to include an abstract on a separate sheet.

Claim 5 was objected to for including an informality. By this Amendment, Applicant has canceled claim 5 thereby making this objection moot.

Claims 1-15 were rejected under 35 U.S.C. § 112, second paragraph. As noted above, by this Amendment, Applicant has canceled claims 1-15 and added new claims 16-23 where claims 16-22 correspond to claims 7, 8, 9, 10, 12, 7 and 14, respectively. New claim 23 is directed to a process for the manufacture of the artifact of claim 22 which is fully supported in the specification as filed and therefore claim 23 does not contain new matter. Further, claim 23 is drawn to the same general inventive concept as claims 16-22 in accordance with PCT Rules 13.1 and 13.2 and thus all claims represent unity of invention in accordance with 37 C.F.R. § 1.475(b)(c) in which claims to different categories of invention are considered to have unity of invention if the claims are drawn to a product and a process specifically adapted for the manufacture of that product.

Specifically with regard to the form of added claims 16-23, Applicant respectfully submits that these claims overcome the previous 35 U.S.C. § 112, second paragraph, rejection to claims 1-15 because objected terms, e.g., hydrophobic moiety, have been

deleted or the claims have been restricted to oligomers formed from dihydroxyaryl carboxylic acids and alkyl diacids, or functional derivatives thereof and supermolecular assemblies formed therefrom.

With regard to the 35 U.S.C. § 112, first paragraph, rejection, since the new claims are directed to specifically characterized entities, Applicant respectfully submits that the rejection under 35 U.S.C. § 112, first paragraph, of now canceled claims 1-15 raised in paragraph 8 of the Office Action have been traversed via the newly added claims 16-23. It is submitted that the specification contains sufficient teaching for those of ordinary skill in the art to manufacture the oligomers of the invention and the aggregates (supermolecular assemblies) formed therefrom as claimed.

Based on the foregoing discussion, Applicant respectfully submits that claims 16-23 are not indefinite and are fully enabled in accordance with 35 U.S.C. § 112, paragraphs 1 and 2.

Claims 1 and 2 were rejected under 35 U.S.C. § 102(b) as being anticipated by Hawley; claims 1-6 were rejected under 35 U.S.C. § 102(b) as being anticipated by Solomons; claims 1, 3-8, 10 and 13 were rejected as being anticipated by Gennari; claims 1-3, 5-10 and 13-15 were rejected under 35 U.S.C. § 102(e) as being anticipated by Hutchins et al (hereinafter "Hutchins"); and claims 1-15 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Graham.

With regard to the rejection of claims 1 and 2 as being anticipated by Hawley where Hawley discloses that water forms a hydrogen bonded network, Applicant respectfully submits that the recitation in claims 16-23 avoid the interpretation of Hawley's water hydrogen bond network from anticipating the claimed invention.

With regard to the remaining references of Solomons, Gennari and Hutchins, Applicant submits that the newly added claims 16-23 are clearly distinguishable over these aforementioned references. One novel and non-obvious feature of claims 16-23 is the provision of carboxyl and hydroxyl groups as hydrogen bonding sites and the restriction of the hydrophobic moiety to the residue of an alkyl diacid.

Specifically, with regard to the Solomon reference, there is no teaching of the use of dihydroxy aryl carboxylic acids in the formation of the lysozyme main chain.

The Gennari reference, although disclosing the use of 2, 6 dihydroxy benzoic acid as the starting material for cyclic polymer, does not suggest that the free carboxyl group participates in the hydrogen bonding. In fact the contrary is indicated in that the carboxyl group is first protected by an ester forming reaction. It is the ethyl and butyl esters which bond. Moreover, there is no teaching of the use of any spacer units and certainly not the alkyl diacids now required for the proposed claims.

Similarly, although Hutchins discloses reactions involving dihydroxy phenyl residues, the residues disclosed do not contain carboxylic groups, they are amides. Moreover, Hutchins fails to provide any teaching or suggestion to use alkyl diacids as the hydrophobic spacer moieties.

Referring now specifically to the rejection of the now canceled claims under 35 U.S.C. § 103 as being obvious from Graham, Applicant submits that new claims 16-23 clearly distinguishes the oligomers of the present invention and the aggregates (supermolecular assemblies) formed therefrom. The polymer of Graham, which could comprise residues of a dihydroxy benzoic acid, does not also contain residues of an alkyl diacid. The reaction of the bisdihydropyran with dihydroxy benzoic

acid, results in a copolymer wherein the monomeric units are covalently bonded to each other. It is this copolymer which is used to entrap the steroid.

There is no teaching or suggestion that the individual polymer molecules are "bound" to each other by hydrogen bonding. Indeed the teaching in the Graham reference is that the polymer scission (degradation), to release the entrapped steroid, is by hydrolysis of the ester groups. There is no suggestion or teaching that the polymer matrix is held together by hydrogen bonds at non-terminal sites on each polymeric unit.

In view of the foregoing discussion, Applicant respectfully submits that new claims 16-23 are not taught or suggested by any of the prior art references which were the subject of the prior art rejections to the now canceled claims 1-15.

In view of the forgoing discussion, Applicant respectfully submits that the present application is now in condition for immediate allowance.

**END REMARKS**